DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0465]

Guidance for Industry on Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications." This guidance is a second revision of the guidance entitled "Major, Minor, FAX, and Telephone Amendments to Original Abbreviated New Drug Applications." FDA's Office of Generic Drugs (OGD) determined that further revision of the policy regarding determination of major, minor, and telephone amendments was necessary to help streamline the review of abbreviated new drug applications (ANDAs).

DATES: Submit written or electronic comments on the guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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FOR FURTHER INFORMATION CONTACT: Rita R. Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications." The guidance is intended to document OGDs policy regarding the determination of major, minor, and telephone amendments to original and supplemental ANDAs. This guidance first published in August 1999 and was originally entitled "Major, Minor, FAX, and Telephone Amendments to Original Abbreviated New Drug Applications." It was revised in May 2000 to explain that the issuance of a major, minor, or FAX amendment would stop the review clock.

The second revision of this guidance (1) deletes the FAX amendment designation, which was found to be unnecessary, (2) now applies to supplemental applications as well, and (3) changes the criteria for determining the type of amendment. The changes in criteria should result in more amendments being categorized as "minor" and fewer as "major." A minor amendment request (generally reviewed within 30 to 60 days) has a higher priority than a major amendment. Since the review of a minor amendment takes place sooner than a major amendment after the original review, there is not a long break in the review process for a minor amendment. The response to a major amendment request, however, goes into the 180-day queue. This process causes a greater time lapse from when the original review was done and results in reviewers having to refamiliarize themselves with the application. It is expected that the new policy will help in moving applications through the approval process more quickly than under the previous policy. Thus the total time for approval of ANDAs will be reduced.

Because it lessens the burden on industry, this guidance is being issued as a Level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR

10.115). As with other Level 1 guidances for immediate implementation, the agency is soliciting comments from the public. This guidance represents the agency's current thinking on major, minor, and telephone amendments to ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 12/3/01

December 3, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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